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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,398	07/16/2003	Stephen Horhota	9/187-2-D2	9542
28509	7590	05/18/2007	EXAMINER	
MICHAEL P. MORRIS			KOSAR, AARON J	
BOEHRINGER INGELHEIM CORPORATION				
900 RIDGEBURY ROAD			ART UNIT	
P O BOX 368			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/620,398	Applicant(s) HORHOTA ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/16/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because **Figure 1, label 16** does not clearly point to any particular part or grouping of parts. Additionally, according to the specification (pages 20 and 27), figure 1 represents the SFE unit as a whole; therefore, designating the entire apparatus as part 16 or grouping all interconnected subparts under a single part label is redundant to the designation and description of figure 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 15 is objected to because of the following informalities: “temperature or” appears to be a typographical error of “temperature, or”. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WETMORE (U.S. Patent 5,514,220) in view of HEIT (U.S. Patent 5,287,632) and MODELL (U.S. Patent 4,061,566).

Wetmore teaches the method of extracting organic material from a porous substrate (claims 4-5) by modulating pressure (claim 1). Wetmore also teaches the importance of modulating pressure to affect supercritical fluid density (column 2, lines 55-57); modulating pressure via two or more pressures (*i.e.* sine waves, square waves, and ascending/descending ramping (column 2, line 60 through column 3, line 7; column 3, lines 11-16)); using supercritical fluid, including supercritical carbon dioxide, scCO₂ (claims 1,3); extraction greater than 50% and

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75% (94%, and 100%; table 1); and motivation to implement the extraction method “suitable for cleaning all items cleaned by prior art methods”, including porous items/items with interstices (column 2, ¶ 1, lines 1-12).

The difference between the teachings of Wetmore and the instant claims, is that while Wetmore teaches extraction from a porous substrate it does not teach a $\leq 30\%$ density interval, sensitive substrates, or porous powders, adsorbents, or absorbents.

Heit teaches a method for removing residual organic solvents (*e.g.* methanol, methylene chloride, mineral oil, etc.: column 4, ¶6) from porous substrates (*e.g.* capsules/compressed tablets adsorbed with gelatin, cellulosic coatings, etc.: claim 1) using scCO_2 (claim 7). Heit also teaches that for supercritical extractions, “it is mandatory (for the solid material) that....physical appearance such as shape, hardness, friability, or color is preserved” and that the suitable supercritical fluid operational temperature and pressure should not adversely affect or decompose the solid material (column 3, ¶4-5). Furthermore, Heit teaches using temperature ranges of 20-65°C and 25-65°C; and, using pressures between 40-1000bar and 40-100bar (column 4, ¶4).

The difference between the teachings of Heit and the instant claims, is that while Heit teaches extraction of porous materials, including sensitive substrates and while Heit also teaches specific supercritical and near-critical temperature and pressure ranges, Heit does not teach modulating pressure; although one of ordinary skill in the art would recognize the method of Wetmore as anticipating cleaning the *item* cleaned by the method of Heit.

Modell teaches a method of using scCO_2 for removing organic adsorbates from polymeric *adsorbents*, including utilizing temperatures of 1.01-1.1 times the critical temperature

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(Modell, column 6, lines 54-62). Modell further teaches an absorption/desorption cycle comprising scCO₂ extraction of an adsorbate from a polymeric adsorbent (Modell, claims 19-22) for additional use with scCO₂ extractions.

Wherein Wetmore recognizes that pressure and temperature - especially as pressure and temperature relate to density, viscosity, and diffusivity of the supercritical fluid - are result-effective variables (column 2, lines 51-57), and in further view of the teachings of Modell and Heit as discussed *supra*, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (*e.g.* temperatures, pressures, heating/cooling or pressurization/depressurization rates, heating/cooling/isothermal or pressurization/depressurization/isobaric times, number and frequency of cycles, etc.), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

Therefore, a person of skill in the art practicing the invention of Wetmore would have been motivated to further incorporate the optimum and the operable conditions, including those taught by Modell and Heit, because these variables are routinely determined and optimized in the art. Absent teachings to the contrary, one would have also had a reasonable expectation for success in identifying optimal conditions for extracting a material from a porous substrate.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, the phrase “sensitive to large changes in pressure, temperature or density” is indefinite because the specification does not identify how to determine or define *sensitivity* or a *large* change in pressure, temperature or density. ‘Sensitive’ and ‘large’ are relative terms, and thus each requires a benchmark from which a comparison can be made. As such, it unclear what substrates are encompassed by the claimed process.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure has been listed on the enclosed PTO-892 form.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0235. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Patent Examiner


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